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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,987	05/25/2006	Tatsuhiko Kodama	14875-152US1 C1-A0306P-US	1443

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	**PAPER NUMBER**
1643	
MAIL DATE	**DELIVERY MODE**
06/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,987	KODAMA ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER H. YAEN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-43* is/are pending in the application.

4a) Of the above claim(s) *17,29 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,18-28,30-38 and 40-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/3/07,11/9/07,5/16/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Re: KODAMA *et al*

1. The amendment filed 3/5/2008 is acknowledged and entered into the record. Accordingly, claims 1-15 are canceled without prejudice or disclaimer, and claims 16-43 are newly added.

2. Claims 16-43 are pending, claims 17,29, and 39 are withdrawn as being drawn to a non-elected invention. The claims are directed to an antibody that inhibits PMF dependent transport as well as method of using an antibody that inhibits PMF transport and is distinct from PepT1 and PepT2 disclosed in the originally presented claims. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 17,29, and 39 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

3. Claims 16,18-28,30-38, and 40-43 are examined on the merits.

Double Patenting Rejections Maintained

The rejection of claims 1-15 under provisional double patenting is moot in view of the cancellation of the claims however the rejection is now applicable to claims 16,18-22, 28,30-38, and 40-43 over claims 15-39 of co-pending application 10/497,900. The rejection is maintained for the reasons already of record. Applicant has requested the rejection to be held in abeyance.

NEW REJECTIONS
Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 16,18-28,30-32,34-36,38, and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liang *et al* (J. Biol. Chem. 1995; 270(12):6456-6463 -- IDS

2/13/06) or Liu *et al* Biochem. Biophys. Acta1995;1235:461-466 – IDS 2/13/06) in view of Campbell (Monoclonal Antibody Technology; 1984; Elsevier Science Publishing Company Inc: pages 1-33), Winter et al (Nature 1991;349:293-299), Basu et al (previously cited 1996 – IDS 9/27/06 #AK or 1998 – IDS 10/22/04 #BG)

a. Liang *et al* and Liu *et al* teach the cloning and characterization of the PepT1 and PepT2 molecules, respectively. Liang et al and Liu et al do not specifically teach monoclonal antibodies to either PepT1 or PepT2, chimeric or humanized antibodies thereof nor method of using the antibodies and antigen binding fragments thereof. However, these deficiencies are remedied by Campbell, Winter, and Basu.

b. Campbell teach that once an antigen/protein is discovered, it would obvious or easy to generate monoclonal antibodies to the new antigen.

c. Winter *et al* discusses the various methods and means of generating man-made antibodies such as humanized antibodies.

d. Basu *et al* teach the use of polyclonal antibodies against PepT1 in cellular ELISAs.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make monoclonal antibodies to either PepT1 or PepT2 because it is routine in the art to make monoclonal antibodies to an antigen once it has been cloned and discovered (see Campbell). Moreover, the manipulation of the antibody to make humanized versions of the antibody, antigen binding fragments is also routine in the art (see Winter et al). Thus those of skill in the art would have been motivated to make

monoclonal antibodies to PepT1 or PepT2 given that the antigen itself was already known and characterized in the prior art. In addition, those of skill in the art would have been motivated to use the monoclonal antibody to either PepT1 or PepT2 in methods of contacting a cell expressing either PepT1 or PepT2 because Basu *et al* teach methods of using polyclonal antibodies in cellular ELISA. The claims do not specifically indicate that the contacting is performed in vivo and therefore the claims read on in vitro cellular assays. Finally, Campbell teaches that monoclonal antibodies have advantages in in vivo therapeutic use over polyclonal antisera because of the its specific targeting ablity. Therefore, those of skill in the art would have been motivated to the monoclonal antibody to either PepT1 or PepT2 as a composition for administration.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 3/5/2008.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER H. YAEN whose telephone number is (571)272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher H Yaen/
Primary Examiner, Art Unit 1643